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35 USC 102(b), and 35 USC \$103(a). However, no response was made with respect to the provisional rejection of claims 1-7 and 10-18 under the judicially created doctrine of obvious:ess type double patenting.

The Examiner provisionally rejected claims 1-18 under the judicially created doctrine of obviousness type touble patenting as being unpatentable over claims 1-9, and 24-27 of copending application number 10/280,324 in view of Itoh et al. (5,080,917).

The obvious type double patenting rejection is analogous to the 35 USC \$103 obviousness analysis.<sup>2</sup> According to \$103, in order to establish a prima facie case of obviousness, there must be (1) some suggestion or motivation to modify the references, (2) reasonable expectation of success and (3) the prior art reference must teach or suggest all of the claim limitations.<sup>3</sup>

The Examiner argues that '324 claims a method of making, and a product thereof, an enzyme-containing granulate suitable for use in an animal feed, but does not disclose that the granules are coated with a polymer. Also, the eximiner believes that Itoh et al. discloses polymer-coated granules for animal feed and a method of making said granules. It is the Examiner's position that it would have been obvious to one skilled in the art to coat the enzyme-containing granules taugh: by '324 with a polymeric substance and that one of ordinary skill would have been motivated to do so because such a coating serves to protect the enzyme from acidic degradation in the stomach of the animal.

The cited references, however, do not teach or suggest the claim limitations of the present invention. According to Applicant's application, and also in light of ner claim 22, a coating of an organic polymer must be applied to an enzymecontaining granulate thereby resulting in a feed additive with an improved pelleting stability. Furthermore, in some embodiments, and as can be seen from new claim 23, Applicant's invention

 $<sup>^{2}</sup>$  Manual of Patent Examining Procedure \$804.B.1  $^{3}$  MFEP \$2143

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comprises a method wherein the coating is applie: in a proportion of about 3 to 25% by weight of the total weight :f the additive.

Alternatively, Itoh et al., teaches coating for an altogether different purpose of allowing delayed release of a physiologically active substance. The coating is adapted to be stable in the first stomach of a ruminant and to be effectively disintegrated in the fourth. Therefore, Itoh e: al. does not teach the limitation to improve pelleting stability.

Additionally, Itoh et al. teaches a coating containing 50% by weight of a water insoluble constituent. Examples of such water-insoluble substance are exemplified, for example, in column 3, lines 43-44. Compounds of this type and used in such a high proportion of more than 50% by weight are unsuitable as coating for a granule to be pelletized. Furthermore, the purpose of the water insoluble substance disclosed in Itoh et al. is to support the disintegration of the coating agent in the fourth stomach of the ruminant. Therefore, application '324 in viev of Itoh et al. does not teach or suggest the limitations of the present invention.

Additionally, the claims of the '324 application do not teach or suggest all the claimed limitations of the Applicant's invention. Though the specification of the '32! application discloses that a coating may be (1) "applied to the granulate to give additional (e.g. flavoured) characteristics or properties like low dust content, colour, protection of the enzyme from the surrounding environment"6 and (2) that the coating can be "fat, wax, polymer, salt, unguent and/or ointment or a coating (e.g. liquid) containing a (second) enzyme or a combination thereof."7, this information is not part of the claims and not pertinent to the present rejection, which as to this reference finds its sole basis in its claims.

Itoh et al. column 3, lines 30-34
Itoh et al. column 4, 15-18

<sup>6 &#</sup>x27;324 application, US 2003/0049811 A1, pg. 3, paragraph 00:3, lines 1-5. <sup>7</sup> '324 application, US 2003/0049811 Al, pg. 3, paragraph 00.3, lines 6-7.

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Even if this disclosure in the specification were available the Examiner, the disclosure is only an unspecified general statement concerning coating of granules, and furthermore the claims and disclosure (to the extent available t: the Examiner) do not disclose use of the coating for the purpose of improving pelleting stability. Furthermore, it is not disclosed how such a coating can be applied or which polymers would b: appropriate. Moreover, the reference can be said to teach away from the present invention because the disclosure concerning pelleting stability on pg. 3 and 4, paragraph 37 relate to incorporating compounds into the granules rather than use as a coating. compounds can be HPMC, HEC, PVA or edible oils. As exemplified in working examples 6 and 7, such polymers or oils are admixed with the enzyme containing carrier and not used as a coating. As such, instead of teaching or suggesting coating :f granules, admixture is taught.

In light of the foregoing, applicant's invention is not an obvious variation of the cited reference and therefore applicant respectfully requests that the obvious type judicially created double patenting rejection be withdrawn.

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Respectfully submitted, NOVAK DRUCE & QUIGG, LLP

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